

CLAIMS

1. A treatment method comprising
providing a balloon mounted on a catheter at a site for treatment within a vascular
system; and
5 pressurizing the balloon to effect a treatment,
wherein
the balloon is pressurized to an inflation pressure which produces a hoop stress
on the balloon wall of about 35,000 psi or more.
- 10 2. A treatment method as in claim 1 wherein the inflation pressure produces a hoop
stress on the balloon wall of from about 35,000 psi to about 65,000 psi.
3. A treatment method as in claim 1 wherein the balloon is formed of a material
comprising a PEN polymer selected from ethylene naphthalate homopolymer and
15 copolymers.
4. A treatment method as in claim 3 wherein the PEN polymer material is
 - a) a polyethylene naphthalate homopolymer or
 - b) a crystallizable copolyester comprising residues of
 - 20 i) ethylene glycol,
 - ii) naphthalene dicarboxylic acid, and
 - iii) at least one PA residue, said PA residue being a member of the group
consisting of residues of terephthalic acid and isophthalic acid, the
naphthalene dicarboxylic acid residues comprising about 5% or more of
25 the sum of naphthalene dicarboxylic acid residues and PA residues in the
copolyester, and,
the balloon characterized by an ability to withstand a hoop stress of at least 50,000 psi
without bursting.
- 30 5. A method as in claim 4 wherein the PEN polymer material is a polyethylene
naphthalate homopolymer.

6. A method as in claim 4 wherein the balloon has at least two structural layers, one being said PEN polymer layer and one being a layer of a second thermoplastic polymer material.
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7. A method as in claim 4 wherein the balloon has inner and outer sides and the second thermoplastic polymer material is a coextruded layer on the outer side thereof.
8. A method as in claim 4 wherein the balloon has an ability to withstand a hoop stress of within the range of 55,000 to 65,000 psi without bursting.
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9. A method as in claim 1 wherein the balloon is formed of a single structural polymer layer.
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10. A method as in claim 1 wherein the balloon has a radial expansion of about 3% or less when inflation pressure is increased from 4 atm to burst.
11. A method as in claim 1 wherein the balloon comprises a structural layer of a crystallizable copolyester comprising residues of
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- i) ethylene glycol,
- ii) naphthalene dicarboxylic acid and
- iii) at least one PA residue, said PA residue being a member of the group consisting of residues of terephthalic acid and isophthalic acid, the naphthalene dicarboxylic acid residues constituting 5-20% of the sum of
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- naphthalene dicarboxylic acid residues and PA residues.
12. A method as in claim 11 wherein said PA residues are terephthalic acid residues.
13. A method as in claim 11 wherein the balloon has a single structural polymer
- 30
- layer.

14. A method as in claim 11 wherein the balloon further comprises a non-structural layer of a lubricious polymer.

15. A method as in claim 11 wherein the balloon further comprises a layer of a
5 second polymer, said second polymer being a polybutylene naphthalate homopolymer or a butylene naphthalate copolymer.

16. A method as in claim 1 wherein the balloon comprises at least two structural layers, one layer being a PEN polymer layer, the PEN polymer material being
10 a) a polyethylene naphthalate homopolymer or
b) a crystallizable copolyester comprising residues of
i) ethylene glycol,
ii) naphthalene dicarboxylic acid and
15 iii) at least one PA residue, said PA residue being a member of the group consisting of residues of terephthalic acid and isophthalic acid, the naphthalene dicarboxylic acid residues at least 80% of the sum of naphthalene dicarboxylic acid residues and PA residues in the copolyester, and
one layer being a polybutylene naphthalate homopolymer or a butylene naphthalate
20 copolymer.